



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-0040]

How to Prepare a Pre-Request for Designation; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "How to Prepare a Pre-Request for Designation (Pre-RFD)." The purpose of this guidance is to explain the Pre-RFD process at the FDA Office of Combination Products (OCP), describe and help a sponsor understand the type of information that the sponsor should include in a Pre-RFD, and assist sponsors in obtaining a preliminary assessment from FDA through the Pre-RFD process. The Pre-RFD process is available to provide informal, non-binding feedback regarding the regulatory identity or classification of a human medical product as a drug, device, biological product, or combination product. In addition, this informal process provides information about a non-combination or combination product's assignment to the appropriate Agency Center (Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), or Center for Biologics Evaluation and Research (CBER)) for premarket review and regulation. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft

guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either written or electronic comments on this collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-D-0040 for "How to Prepare a Pre-Request for Designation (Pre-RFD); Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not

in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues to the Office of Management and Budget in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or email to oir_submission@omb.eop.gov. All comments should be identified with the title, "How to Prepare a Pre-Request for Designation (Pre-RFD); Draft Guidance for Industry."

Submit written requests for single copies of the draft guidance document entitled "How to Prepare a Pre-Request for Designation (Pre-RFD)" to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8619. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Leigh Hayes, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993-0002, or via email at combination@fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Since its establishment on December 24, 2002, OCP has served as a resource for sponsors at various stages of development of their product. Sponsors often seek OCP feedback on whether their medical product will be regulated as a drug, a device, a biologic, or a combination product, and which FDA medical product Center (CDER, CBER, or CDRH) will regulate it, if it is a non-combination product, or will have the primary jurisdiction for the premarket review and regulation of the product, if it is a combination product.

There are two ways that a sponsor can receive such feedback from OCP. One option is to submit an RFD to receive a formal, binding determination for the sponsor's product with respect to classification and/or center assignment that may be changed under conditions specified in section 563 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-2) and 21 CFR 3.9 in the regulations. The RFD process is codified in 21 CFR Part 3, and OCP has issued a guidance about this process (see "How to Write a Request for Designation" at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126053.htm>). A second more flexible option is for a sponsor to submit an inquiry to OCP to receive a preliminary jurisdictional assessment, which is not binding.

Many sponsors seek to utilize the flexibility of more approachable ways to interact with OCP and the medical product Agency Centers to obtain feedback from the Agency before submitting a marketing application to FDA. Over time, these informal methods of obtaining

feedback have become increasingly customary with sponsors, and for some, even preferable to the formal RFD process. Accordingly, FDA is enhancing the transparency and consistency of this process, which will now be called the "Pre-Request for Designation (Pre-RFD) Program."

This draft guidance describes this structured process with clear recommendations for sponsors wishing to submit Pre-RFDs. It also provides the process for review of Pre-RFDs by FDA staff, the general timeframes for sponsors to receive feedback from OCP, and the process for scheduling teleconferences and meetings in relation to a Pre-RFD.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on how to prepare a Pre-RFD. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (the PRA) (44 U.S.C. 3501-3502), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Draft Guidance for Industry; How to Prepare a Pre-Request for Designation (Pre-RFD)

This draft guidance describes how to prepare a Pre-RFD. The guidance provides recommendations regarding the information that should be submitted in a Pre-RFD request and procedures that should be followed for meetings or conference calls between OCP, the Centers, and industry representatives or sponsors.

The proposed collections of information are necessary to allow the Agency to receive Pre-RFD requests in order to implement this voluntary submission program.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Pre-RFD submissions	136	1	136	12	1,632
Pre-RFD meetings	136	1	136	1	136
Total					1,768

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents are product sponsors and industry representatives subject to FDA's laws and regulations. FDA estimates that it will receive approximately 136 Pre-RFDs annually. The Agency reached this estimate through its experience with the formal Request for Designation (RFD) program, by reviewing the number of informal, pre-RFD inquiries from sponsors that the Agency received over the past 3 years. Based on FDA's experience with these informal, Pre-RFD inquiries, FDA expects the proposed Pre-RFD program to be utilized as a viable program in the future and expects that the number of Pre-RFDs will increase initially to approximately 180 submissions.

FDA estimates from past experience with informal Pre-RFD inquiries that the complete process involved with preparing the Pre-RFD submission takes approximately 12 hours and an additional 1 hour for meetings.

This average is based upon estimates by FDA administrative and technical staff who are familiar with the information collection relating to informal, Pre-RFD inquiries, who have consulted and advised sponsors and industry representatives on the information collection, and who have reviewed the documentation submitted.

Therefore, the total reporting burden hours is estimated to be 1,768 hours.

Table 2.--Estimated Annual Reporting Burden¹

No. of Respondents	Total Burden Hours Annualized	Hourly Wage Rate	Total Cost Annualized
136	13	\$33.26	\$58,803.68

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Assuming an hourly wage plus benefit rate of \$33.26¹, the result is a cost of \$432.38 per respondent. The estimated submission cost of \$432.38 multiplied by 136 submissions per year equals \$58,803.68, which is the estimated aggregated industry reporting cost annualized.

This draft guidance also refers to previously approved information collections found in FDA regulations. The collections of information in 21 CFR part 3 are approved under OMB control number 0910-0523.

IV. Electronic Access

Persons with access to the Internet may obtain the document at
<http://www.fda.gov/RegulatoryInformation/Guidances/ucm534661.htm>.

Dated: January 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

¹ Wage is based on the 2015 Bureau of Labor Statistic's survey, National Industry Specific Occupational Employment and Wage Estimate, for standard occupational code 13-1041, compliance officer in pharmaceutical and medicine manufacturing (<http://www.bls.gov/oes/current/oes131041.htm>).

